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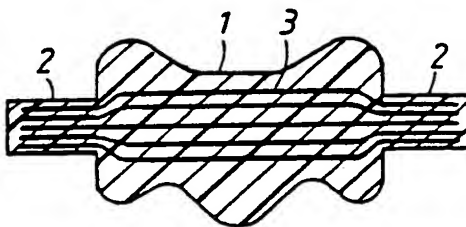
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(57) Abstract

An artificial joint mechanism with a flexible mid-section and which, by means of said connecting members or pins, cooperates with anchoring members arranged in the bone tissue. At least the mid-section of the joint mechanism is provided with suitable reinforcements in the form of fibers, strips, layer, etc. of a suitable flexible, resilient material to optimally impart normal joint function, partly in order to guarantee the ability of the artificial joint to withstand repeated bending stress and partly to provide the artificial joint with a necessarily limited pivotability. The reinforcement has various configurations and are either inside or outside the mid-section and usually extending along the body toward the end pins.

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ARTIFICIAL JOINT MECHANISM

The present invention relates to an artificial, elastic joint mechanism intended for use in reconstructing joints such as finger joints, wrists, ankles, elbows, hip-joints, knees, toe joints and other joints in the human body. The joint mechanism can also be used to replace disc functions in the spine.

A joint body for joint prostheses consisting entirely of an elastomeric material is described, for instance, in US Patent 3,875,594. This known body is provided with pins protruding from its opposing short sides and formed in one piece with the body, said pins being designed to fit into cavities in respective bone pipes. This direct anchoring of the joint body in the bone tissue has been found to give rise to serious drawbacks, such as undesired wear between the pins and the surrounding tissue upon movement of the joint, with consequent risk of inflammation and tissue damage.

To eliminate the latter drawback, according to Swedish patent Application No. 87 04 211-5 corresponding to US Application No. 473,992, filed May 2, 1990 a combination is suggested comprising a mid section of resilient material arranged as a joint body between a pair of pins, the pins being attached by means of flanges embedded in the material and arranged transversely to the pins, and a tubular screw for each pin which can be secured in the bone, into which the pin is inserted, the pins and screws consisting of a biocompatible material. This construction has enabled better anchoring of the joint prosthesis in the bone pipes than was possible in the construction according to US Patent 3,875,594 mentioned above.

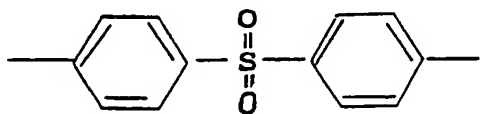
However, it has been found that the joint body used in both the above-mentioned constructions, which consists of silicon rubber or polyurethane, is not satisfactory with respect to the expectations which must be placed on such an

artificial joint. First of all, there is considerable risk of tissue damage and inflammation due to the constant movement of the pins in the tissue or in the attachment member. Furthermore, it has been found in practice that the joint body itself is not sufficiently strong in the environment in which it is used. A certain bending resistance is desired in such joint bodies, i.e. a more or less directed bending function, in order to emulate the normal function of a joint as much as possible.

An object of the present invention, therefore, is to achieve a joint body which is more durable in use, and which can be optimally adjusted to the bending function of the joint it is replacing.

This and other objects are achieved by providing an artificial joint mechanism for replacing a natural joint comprising a joint body which includes a flexible mid-section, connecting means for connecting said joint body to bone tissue and reinforcement means for resiliently maintaining in said joint body in its original shape following repeated deformations of said joint body in its main bending direction, said reinforcement means connected to at least said flexible mid-section.

According to a suitable embodiment of the invention, the mid-section with protruding pins, if any, consists of a thermoplast containing di-phenyl-sulphone groups of the type



The material proposed, according to the invention, has the ability to return to its original form to at least 80 % after repeated, varying deformations. That means that it will not return 100% to its original shape but nearly to

that shape, i.e. about at least 80 %.

5 According to a preferred embodiment of the invention, the reinforcement consists of a number of fibers embedded longitudinally in the mid-section, said fibers extending along the direction of movement of the mid-section and continuing into the pins.

10 The reinforcement may suitably be comprised of titanium threads, carbon fibers, polymer fibers, cable-like twisted fibers, a mesh of plastic or metal, suitably titanium, woven inserts of biocompatible material, relatively thin strips or plates of primarily biocompatible material, preferably titanium, and the like.

15 The reinforcement of a selected material may suitably be in the form of a number of layers of pre-fabricated strips, plates, or net-like inserts arranged one on top of the other, with spacing between, along the mid-section, the
20 narrowing end portions of those layers, strips, etc., extending into the end pins.

25 In order to obtain special joint effects, a part of the reinforcement may be arranged transverse to the normal direction of movement of the joint, or as a three-dimensional space pattern with certain diagonal reinforcements in the joint body.

30 The reinforcement can also be arranged outside the actual joint body in the form of a spiral coil surrounding at least the mid-section. In another embodiment the spiral or helix is embedded in the joint body mid-section.

35 So as not to affect the surrounding tissue, the joint mechanism may be arranged in a sleeve-shaped outer casing surrounding at least the mid-section. That outer casing may be suitably comprised of titanium.

The joint body mid-section typically is of an elongate, generally similar cross section shape, with thickness variation for optimum support and bendability. In one preferred embodiment, the body is generally half spherical, with the connecting means or end pins respectively projecting from the flat side and the rounded side of the joint body mid-section.

The joint mechanism described herein includes reinforcement to optimize flexibility in the main bending direction of the reconstructed joint and/or pivotability of the joint mechanism.

Other features and advantages of the present invention will become apparent from the following description of the invention which refers to the accompanying drawings.

Figure 1 shows a section through a joint body reinforced in accordance with the invention;

Figure 2 shows a section through another embodiment of a joint body according to the invention; and

Figures 3-5 show additional alternate embodiments, Figure 4 in section, and Figures 3 and 5 in perspective views.

Figures 6-9 show sections through further embodiments of a joint body according to the invention with the "a" Figures showing transverse sections and the "b" Figures showing top view cross sections.

Figure 10 is a perspective of a further embodiment of a joint body.

Figure 11 is a top view cross section through yet another embodiment.

Figure 12 is a top view cross section through a still further embodiment.

5 Figure 13 is a top view of yet another embodiment of a joint body.

Figure 14 is a side view thereof.

10 Referring to the drawings, a joint body is designated 1. When the joint body 1 is used together with anchoring elements screwed into respective bones, the joint body 1 is provided with a pair of protruding pins 2 intended to cooperate with cavities arranged in the anchoring elements.

15 However, the joint body 1 may also be shaped without protruding pins if it is to be used as a joint mechanism for constructions described in United States patent application No. 406,587, filed September 13, 1989.

20 The joint body 1 preferably comprises an elastomeric material, and in the embodiment according to Fig. 1 it is provided with reinforcement means 3 in the form of a number of fibers extending longitudinally through the mid-section between pins 2 and out into the pins.

25 Reinforcement means 3 may consist, for instance, of titanium threads, carbon fibers, polymer fibers, cable-like twisted fibers, mesh of plastic or metal, suitably titanium, woven inserts of biocompatible material, thin strips, 30 or thin plates, of primarily biocompatible material, preferably titanium or the like.

In the embodiment according to Fig. 2, reinforcement means 3 consists of a wire 4 of titanium. Here, also, reinforcement means 3 suitably extends out into the pins 2. 35

In the embodiments according to Figs. 1 and 2, reinfor-

cement means 3 has been embedded into the joint body 1 and the pins 2 by means of injection molding, so that the elastomeric material surrounds the reinforcement of the actual pins 2, as well.

5

In the embodiment according to Figs. 3, 4 and 5, the reinforcement 3 has a special configuration in which the end portions 4 which are to form the pins 2 have been compressed an are, therefore, not necessarily embedded in the elastomeric material.

10

Figs. 6-12 show some principles as to the structure of the reinforcement 3.

15

According to Figs. 6a and b, thus, the reinforcement 3 may consist of a number of thin strips 5, or plates 5, of titanium foil, for instance, arranged spaced from each other, their narrowing end portions 6 and 7 extending into the pins 2.

20

According to Figs. 7a and b, the reinforcement 3 consists of a number of layers 8 of thin threads 9, the ends of which continue into the pins 2.

25

According to Figs. 8a and b, the reinforcement 3 consists of one or more layers 10 of a net-like insert 11.

30

According to Figs. 9a and b, one or more layers 10 of a woven material 11 are used to form the reinforcement 3.

35

The flexibility and elasticity of joint bodies 1, reinforced in such manner, can be governed as to direction and strength, depending on where the reinforcement is placed in the section and in which plane it is spread.

Depending on the desired degree of flexibility, control, etc., the reinforcement may also be given various three-

dimensional embodiments. For instance, according to Fig. 10, the reinforcement may be arranged spirally around the joint body, i.e. it is a fiber 12 wrapped spirally around the pins at the ends of the body and around the body itself. The reinforcement may be on the joint body in some other suitable manner in order to achieve the desired optimization with respect to limited flexibility, compression, etc.

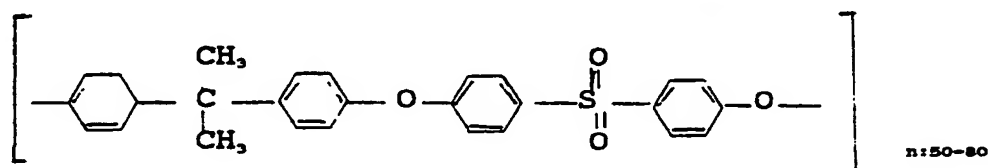
10 The reinforcement can also be applied outside the actual joint body in the form of a spiral, as in Fig. 10, or the like. The fibers may run diagonally in the joint body itself as with the fibers 14, 15 in Fig. 11. Some fibers 14 are in the body and some fibers 15 extend from pin to pin.

15 As in Fig. 12, the entire joint body 1 with the reinforcement 16 located either outside or inside the body itself can be surrounded by a biocompatible sleeve 17 of titanium, for instance, suitably with slight clearance, so that the surrounding tissue is not affected directly by bending movements of the joint body.

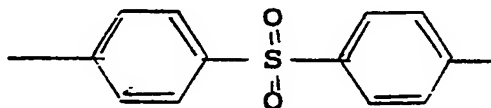
In the embodiment of Figs. 13 and 14, the joint body 1 has a generally half spherical shell 21 including a rounded body with a flat end wall 22. The shell surrounds and defines the shape of the elastomeric material body. The pin 2 at one end is integral with and of the material of the body 1. The pin 2a at the other end of the joint body projects out from the flat end wall 22 and is an integral end portion of the internal reinforcement 23, which is in the form of a helical coil which decreases in cross section toward the pin 2a. This embodiment has a special advantage in a joint. It permits a certain degree of rotation of the joint body with reference to the adjacent bone, to the extent permitted by the pins 2.

According to a preferred embodiment of the invention, the

elastomeric material used for the joint body 1 may be a thermoplastic containing di-phenyl-sulphone groups, characterized by good elasticity, high durability and notch impact strength. In the present example, a poly-sulphonic plastic marketed by Amoco Performance Products, Inc. under the trade name UDELL, designation P1700, is used. This poly-sulphonic plastic is produced by a nucleophilic substitution reaction between the di-sodium salt of Bisphenol A and 4,4-di-chlor-di-phenyl sulphone. The chemical structure then has the following appearance:



The most important constituent is the di-phenyl sulphone group



Ether and the isopropylidene have been connected to the di-phenyl-sulphone group in order to give the material elasticity, as well as high strength. The material properties are as follows:

Tensile strength	70 N/mm ²
Tension modulus	2480 N/mm ²
Impact strength	40 Kj/m ²

Preferred tensile strength is between 50 and 90 N/mm². Preferred modulus of elasticity is between 2000 and 2600 N/mm². Preferred notch impact strength is between 40 and 80 J/n (with a material thickness of 2.8-15.0 mm).

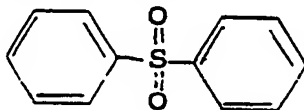
It should also be pointed out here that the polysulphonic plastic is inert with respect to the tissue fluid and is

substantially impervious to water. The ability of the material to regain its original form after repeated, varying deformations is about at least 80%, that is, it does not fully restore to its original shape by itself. The
5 notch impact strength stated above was measured with material thickness of between 2.8 and 15.0 mm.

The invention is, of course, not limited to the embodiments described above and the reinforcements can be effected in
10 many ways in order to provide optimal joint function for every occasion. Although the present invention has been described in relation to particular embodiments thereof, many other variations and modifications and other uses will become apparent to those skilled in the art. It is preferred,
15 therefore, that the present invention be limited not by the specific disclosures herein, but only by the appended claims.

C l a i m s

1. An artificial joint mechanism for replacing a natural joint and c o m p r i s i n g a joint body (1) which includes a flexible mid-section, connecting means (2) for connecting said joint body (1) to bone tissue, and reinforcement means (3) in at least said flexible mid-section for optimizing flexibility of said mid-section in the main bending direction of the joint mechanism and/or the pivotability of the joint mechanism.
2. The artificial joint mechanism of claim 1, w h e r e i n said connecting means (2) comprises a pair of pins connected to said flexible mid-section and protruding therefrom for cooperation with anchoring members implanted in the bone tissue on each side of the joint.
3. The artificial joint mechanism of claim 1, w h e r e i n said reinforcement means (3) is shaped and comprised of a material for resiliently maintaining said joint body (1) in its original shape following repeated deformations of said joint body (1) in its main bending direction.
4. The artificial joint mechanism of claim 1, w h e r e i n said mid-section is comprised of an elastomeric material.
5. The artificial joint mechanism of claim 4, w h e r e i n said mid-section is comprised of a thermoplastic containing di-phenyl-sulphone groups of the type



6. The artificial joint mechanism of claim 5, w h e r e i n said mid-section has an ability to return to

its original form of at least 80% after repeated, varying deformations.

7. The artificial joint mechanism of claim 4,
5 w h e r e i n said mid-section has an ability to return to its original form of at least 80% after repeated, varying deformations.

8. The artificial joint mechanism of claim 5,
10 w h e r e i n said mid-section is comprised of a polymeric material having a tensile strength of between 50 and 90 N/mm², a modulus of elasticity of between 2000 and 2600 N/mm² and a notch impact strength of between 40 and 80 J/n (with a material thickness of 2.8-15.0 mm).

15 9. The artificial joint mechanism of claim 4, w h e r e i n said mid-section is comprised of a polymeric material having a tensile strength of between 50 and 90 N/mm², a modulus of elasticity of between 2000 and 2600
20 N/mm² and a notch impact strength of between 40 and 80 J/n (with a material thickness of 2.8-15.0 mm).

10. The artificial joint mechanism of claim 3, w h e r e i n said mid-section is comprised of a polymeric
25 material having a tensile strength of between 50 and 90 N/mm², a modulus of elasticity of between 2000 and 2600 N/mm² and a notch impact strength of between 40 and 80 J/n (with a material thickness of 2.8-15.0 mm).

30 11. The artificial joint mechanism of claim 2, w h e r e i n said mid-section and pins are comprised of a polymeric material having a tensile strength of between 50 and 90 N/mm², a modulus of elasticity of between 2000 and 2600 N/mm² and a notch impact strength of between 40 and 80
35 J/n (with a material thickness of 2.8-15.0 mm).

12. The artificial joint mechanism of claim 1,

w h e r e i n said reinforcement means (3) comprises at least one fiber embedded in and extending longitudinally along said mid-section and extending along a direction of movement of said mid-section.

5

13. The artificial joint mechanism of claim 1, w h e r e i n said reinforcement means (3) comprises at least one reinforcement element extending along said joint body (1) selected from the group consisting of titanium
10 threads, carbon fibers, polymer fibers, cable-like twisted fibers, plastic or metal mesh, woven inserts comprising biocompatible material, and thin strips or plates comprising biocompatible material.

15

14. The artificial joint mechanism of claim 1, w h e r e i n said reinforcement means (3) comprises a plurality of layers of a reinforcement element selected from the group consisting of prefabricated strips, plates and net-like inserts, whereing said layers are substantial-
20 ly parallel to and spaced from each other wherein said layers extend through said mid-section and into said connecting means (2).

25

15. The artificial joint mechanism of claim 14, w h e r e i n said connecting means (3) are narrower in cross section than said mid-section and wherein said layers are narrower in said connecting means (3) than in said mid-section.

30

16. The artificial joint mechanism of claim 1, w h e r e i n said reinforcement means (3) includes a reinforcement element transverse to a normal direction of movement for said joint.

35

17. The artificial joint mechanism of claim 1, w h e r e i n said means includes a reinforcement means (3) which spreads in three dimensions in said joint body (1).

18. The artificial joint mechanism of claim 1,
w h e r e i n said reinforcement means (3) is a spiral
coil surrounding said mid-section.

5 19. The artificial joint mechanism of claim 1, further
c o m p r i s i n g a sleeve-shaped outer casing
surrounding at least said mid-section.

10 20. The artificial joint mechanism of claim 19,
w h e r e i n said outer casing comprises titanium.

21. The artificial joint mechanism of claim 1,
w h e r e i n said reinforcement means (3) comprises a
plurality of reinforcing elements extending through said
15 joint body (1) and at least one of said elements being in a
plane diagonal to said joint body (1).

22. The artificial joint mechanism of claim 4,
w h e r e i n said body is generally half spherical in
20 shape with a flat side, and one of said connecting means
(2) extending out of said flat side; said body having a
rounded side and another of said connecting means (2)
projecting from said rounded side.

25 23. The artificial joint mechanism of claim 1,
w h e r e i n said body is generally half spherical in
shape with a flat side, and one of said connecting means
(2) extending out of said flat side; said body having a
rounded side and another of said connecting means (2)
30 projecting from said rounded side.

24. The artificial joint mechanism of claim 23,
w h e r e i n said reinforcement means (3) comprises a
helically coiled wire in said body and the helix of said
35 coil extending toward said connecting means (2).

25. The artificial joint mechanism of claim 24,

w h e r e i n said coil is wound wider in diamter toward said rounded side of said body and is wound gradually smaller in diameter toward said flat side of said body.

- 5 26. The artificial joint mechanism of claim 25,
w h e r e i n said connecting means (2) at said flat side
of said body is a pin integral with said coil.

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Fig. 1

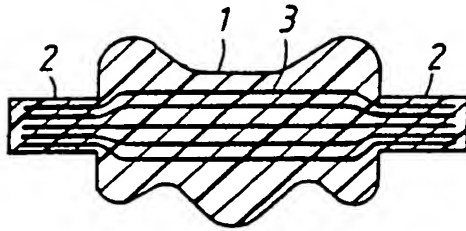


Fig. 2

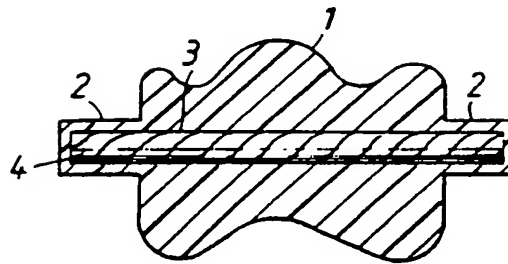


Fig. 3

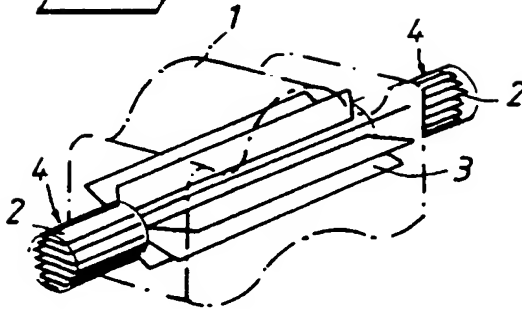


Fig. 4

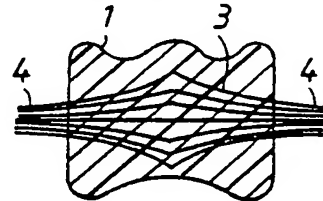


Fig. 5

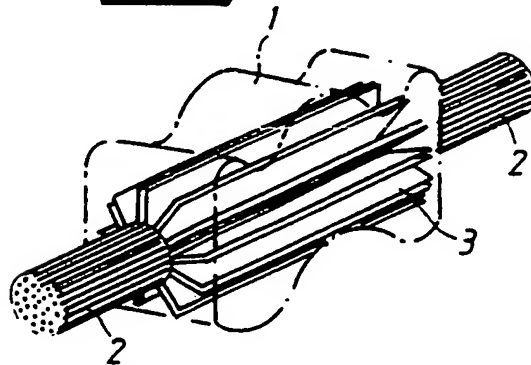


Fig. 6

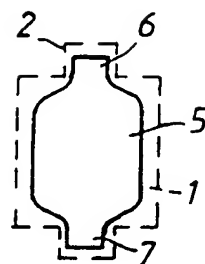
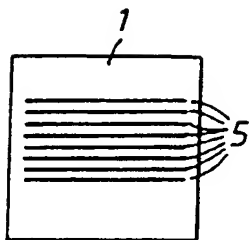


Fig. 7

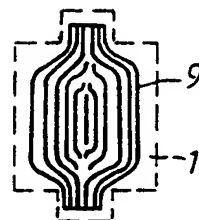
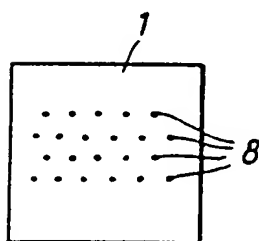


Fig. 8

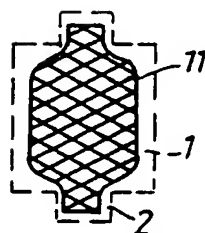
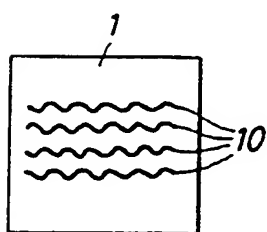
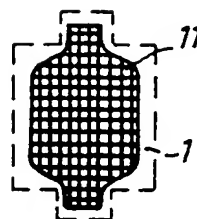
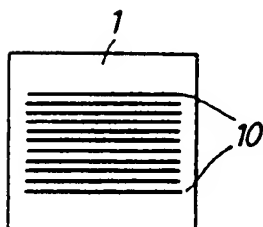


Fig. 9



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Fig. 10

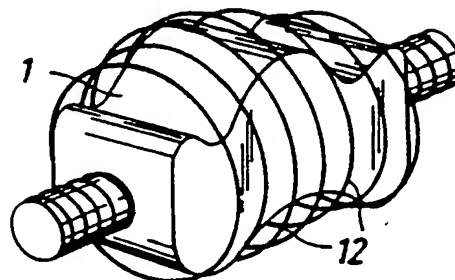


Fig. 12

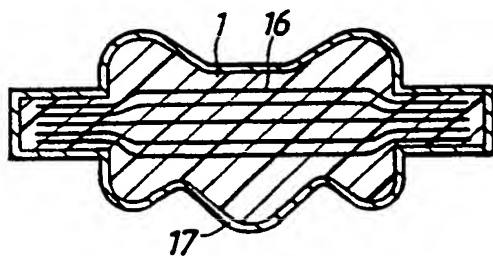


Fig. 11

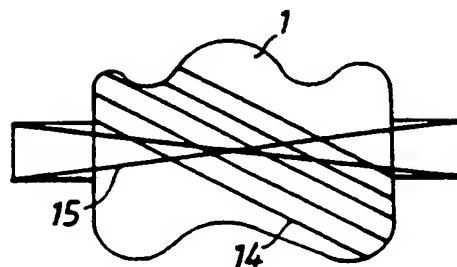


Fig. 13

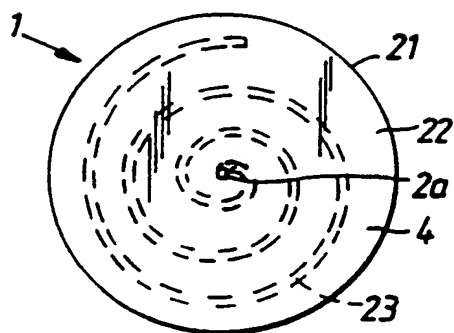
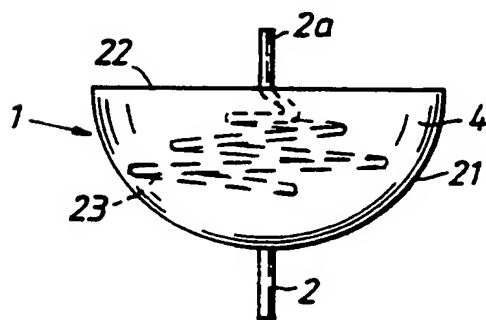


Fig. 14



INTERNATIONAL SEARCH REPORT

International Application No PCT/SE 91/00286

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶ According to International Patent Classification (IPC) or to both National Classification and IPC IPC5: A 61 F 2/30						
II. FIELDS SEARCHED <div style="text-align: center; border-top: 1px solid black; border-bottom: 1px solid black; margin: 5px 0;">Minimum Documentation Searched⁷</div> <table style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 20%; border: 1px solid black; text-align: left; padding: 2px;">Classification System</th> <th style="border: 1px solid black; text-align: left; padding: 2px;">Classification Symbols</th> </tr> <tr> <td style="border: 1px solid black; padding: 10px; vertical-align: top;">IPC5</td> <td style="border: 1px solid black; padding: 10px; vertical-align: top;">A 61 F</td> </tr> </table> <div style="text-align: center; border-top: 1px solid black; border-bottom: 1px solid black; margin: 5px 0;">Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in Fields Searched⁸</div>			Classification System	Classification Symbols	IPC5	A 61 F
Classification System	Classification Symbols					
IPC5	A 61 F					
SE,DK,FI,NO classes as above						
III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹						
Category *	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³				
X	US, A, 3593342 (JOHN J. NIEBAUER) 20 July 1971, see column 1, line 59 - column 2, line 25 <div style="text-align: center;">--</div>	1-4,9- 14,17, 19				
X	US, A, 3886600 (KAHN ET AL) 3 June 1975, see column 4, line 65 - column 6, line 33 <div style="text-align: center;">--</div>	1-4,9- 17,19- 21				
A	US, A, 4313232 (HABAL ET AL) 2 February 1982, see the whole document <div style="text-align: center;">--</div>	1-4,9- 11				
A	US, A, 4634445 (HELAL) 6 January 1987, see the whole document <div style="text-align: center;">--</div> <div style="text-align: center;">-----</div>	1-4,9- 13,18, 24,26				
<div style="display: flex; justify-content: space-between;"> <div style="width: 48%;"> <p>* Special categories of cited documents:¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 48%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p> </div> </div>						
IV. CERTIFICATION						
Date of the Actual Completion of the International Search 28th June 1991		Date of Mailing of this International Search Report 1991 -07- 1 6				
International Searching Authority <div style="text-align: center; margin-top: 10px;"> SWEDISH PATENT OFFICE </div>		Signature of Authorized Officer <div style="text-align: center; margin-top: 10px;"> Leif Karnsäter </div>				

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
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This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the Swedish Patent Office EDP file on **91-05-29**.
The Swedish Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

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